DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-122/S-046
NDA 17-122/S-047

Lilly Research Laboratories
Attention: Timothy R. Franson, M.D.
Executive Director, North American Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Franson:

Please refer to your supplemental new drug applications dated April 22, 1996, received April 23, 1996 (S-046) and June 11, 1996, received June 17, 1997 (S-047) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Darvocet N (propoxyphene napsylate and acetaminophen) 50 and 100 mg Tablets.

Please note, S-046 was incorrectly coded by our document room as a supplement when it was actually just an electroniuc copy of the most recently approved labeling requested by a reviewer. Therefore, S-046 is being sdministratively closed in our files.

S-047, a "Changes Being Effected" supplemental new drug application provides for revisions to the HOW SUPPLIED section of the package insert (revised for ease of reading), and the OTHER INFORMATION section of the Patient Information, to delete a photograph of Darvon Capsules.

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted June 11, 1996). Accordingly, this supplemental application is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Carmen DeBellas, Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Jonca Bull, M.D.
Acting Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jonca Bull

10/30/01 11:55:43 AM